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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/591,395

08/22/2007

Guido Grandi

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05/05/2008

NOVARTIS VACCINES AND DIAGNOSTICS INC.

INTELLECTUAL PROPERTY R338

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EXAMINER

BASKAR, PADMAVATHI

ART UNIT

PAPER NUMBER

1645

MAIL DATE

DELIVERY MODE

05/05/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/591,395

Applicant(s)

GRANDI ET AL.

Examiner

PADMA v. BASKAR

Art Unit

1645

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 September 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6, 11, 12, 15-28, 30 and 31 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-6, 11, 12, 15-28, 30 and 31 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

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DETAILED ACTION

RESTRICTION

1 Applicants preliminary amendment filed on 9/1/06 has been entered.

Claims 7-10, 13-14 and 29 have been canceled.

Claims 1-6, 11-12, 15-28 and 30-31 are pending in the application.

2. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted.

Groups 1-7 , claim(s) 1-6 and 24-28 (polypeptide) 15-20 (composition) , and 21-23 (method of making composition) drawn to a polypeptide SEQ.ID.NO:54 (CPn0794) , SEQ.ID.NO:6 (CPn0795) , SEQ.ID.NO:55 (CPn0796), SEQ.ID.NO:56 (CPn0797) ,SEQ.ID.NO:78 (CPn0798) , SEQ.ID.NO:79(CPn0799) , and SEQ.ID.NO:86 respectively, a composition and a method of making composition comprising one , two or more said polypeptides.

Groups 8-14 , claim(s) 11 and 30 drawn to a method of eliciting an immune response comprising administering a polypeptide SEQ.ID.NO:54 (CPn0794) , ,SEQ.ID.NO:6 (CPn0795) , SEQ.ID.NO:55 (CPn0796), SEQ.ID.NO:56 (CPn0797) ,SEQ.ID.NO:78 (CPn0798), SEQ.ID.NO:79(CPn0799) , and SEQ.ID.NO:86 respectively.

Group 15-21 , claim(s) 12 and 31 drawn to a method of diagnosing an immune response comprising contacting biological sample with a binding agent that binds to polypeptide SEQ.ID.NO:54 (CPn0794) , ,SEQ.ID.NO:6 (CPn0795) , SEQ.ID.NO:55 (CPn0796), SEQ.ID.NO:56 (CPn0797) ,SEQ.ID.NO:78 (CPn0798) , SEQ.ID.NO:79(CPn0799) and SEQ.ID.NO:86 respectively.

The technical feature of linking groups appears to be that they are all related to polypeptides. However, WO 02-02606 disclose a polypeptide comprising an amino acid sequence SEQ.ID.NO: 85 (see page 83, example 43 , the examiner is sending the relevant page 83 only) from *C. pneumoniae* and is 100 % identical to the claimed polypeptide

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SEQ.ID.NO: 54. Therefore, the technical feature of linking groups 1-21 does not constitute a special technical feature as defined by PCT Rule 13.2, as it does not define a contribution over the prior art and hence unity of invention is lacking.

The special technical feature of Group 1-7 is considered to be polypeptide which is made up of amino acids.

The special technical feature of Groups 8-21 is considered to be methods utilizing polypeptides that share no common special technical feature because the polypeptide have no common structure (i.e., no common sequence) property and function so as to form a single general inventive concept under Rule 13.1. Hence, unity is lacking among groups .

Accordingly, Groups 1-21 are not so linked by the same or a corresponding special technical feature as to form a single general inventive concept.

The claimed polypeptide SEQ.ID.NO:54 (CPn0794), SEQ.ID.NO:6 (CPn0795), SEQ.ID.NO:55 (CPn0796), SEQ.ID.NO:56 (CPn0797),SEQ.ID.NO:78 (CPn0798), SEQ.ID.NO:79 (CPn0799), and SEQ.ID.NO:86 share no common special technical feature because these polypeptides have no common structure (i.e., no common sequence) .

3. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention

4. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

5. Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Fax Center, which receives transmissions 24 hours a day and 7 days a week. The transmission of such papers by facsimile must conform to the notice published in the Official Gazette, 1096 OG 30, November 15, 1989. The Right Fax number is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PMR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PMR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PMR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you

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would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Padma Baskar Ph.D., whose telephone number is ((571) 272-0853. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 6.30 a.m. to 4.00 p.m. except First Friday of each bi-week.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shanon Foley can be reached on (571) 272-0898.

Respectfully,

/Padma v Baskar/

Examiner, Art Unit 1645